

Remarks/Arguments

Claims 1 to 8, 21 to 25, 31 and 32 are pending. Claims 9 to 20 have been cancelled. New Claims 31 and 32 have been added, and are drawn to the elected invention, and are supported by original Claim 8. Claims 1, 3, 8 and 25 have been amended. Claims 8 and 25 have been amended to avoid duplication with Claim 1 and to eliminate scope problems.

The Office Action stated that restriction is required under 35 U.S.C. 121 and 372. Applicants assert that Groups I to IV form a single general inventive concept and should be included together in the restriction requirement.

The Office Action stated that Claims 1 to 30 are drawn to more than one inventive concept (as defined by PCT Rule 13), and, accordingly, a restriction is required according to the provision of PCT Rule 13.2. Applicants traverse this restriction requirement because there is unity of invention, for example, between Groups I to IV. Applicants request that the Examiner modify the restriction requirement so as to combine Groups I to IV as one general inventive concept under the principal of unity of invention.

The Office Action stated that PCT Rule 13.1 states that the international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept (requirement of unity of invention). Applicants assert that Groups I to IV are a group of invention so linked as to form a single inventive concept that amounts to unity of invention.

Section 803.2 of the M.P.E.P. (Rev. 5) states:

“Since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and *In re Haas*, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unit of invention. *In re Harnisch*, 631 F.2d, 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature essential to that utility.” [Emphasis Supplied]

In independent Claim 1, R¹ and R² are each defined as a Markush group. In the Examiner's definition of each Groups I to IV, R² is stated to be as defined in Claim 1 (i.e., in a Markush group with broad or subgeneric members). Further, in each of Groups I to IV, R¹ is C₁₋₈-alkyl, phenyl, furanyl and thienyl, respectively. All of these species or subgroup provide the same utility in the invention, and share a substantial structural feature essential to that utility. The definition of R¹ in Groups I to IV, in essence, form a Markush group that has unity of invention.

Section 803.2 of the M.P.E.P. (Rev. 5) further states:

“However, when the Markush group occurs in a claim reciting a process or a combination (not a single compound), it is sufficient if the member of the group are disclosed in the specification to possess at least one property in common which is mainly responsible for their function in the claimed relationship, and it is clear from their very nature or from the

prior art that all of them possess this property. Inventions in metallurgy, refractories, ceramics, pharmacy, pharmacology and biology are most frequently claimed under the Markush formula but purely mechanical features of process steps may also be claimed by using the Markush style of claiming.” [Emphasis Supplied]

This application is a national stage application of an international application. Section 1850.I of the M.P.E.P. (Rev. 5) states:

“Any international application must relate to one invention only or to a group of inventions so linked as to form a single general inventive concept (PCT Article 3(4)(iii) and 17(3)(a), PCT Rule 3.1, and 37 CFR 1.475). Observance of this requirement is checked by the International Searching Authority and may be relevant in the national (or regional) phase.” [Emphasis Supplied]

The I.S.A. did not find any lack of unity. See the enclosed copy of the cover sheet (Form PCT/IPEA/409) of applicants’ International Application No.

PCT/EP03/07411. Section 1875 of the M.P.E.P. (Rev. 5) states:

“The examiner will usually begin the preliminary examination by checking the international application for unity of invention. The international preliminary examination will only be directed to inventions which have been searched by the International Searching Authority. All claims directed to inventions which have not been searched by the International Searching Authority will not be considered by the International Preliminary Examining Authority. If the examiner in the

International Preliminary Examining Authority finds lack of unity of invention in the claims to be examined, an invitation is normally prepared and sent to the applicant requesting the payment of additional fees or the restriction of the claims on Form PCT/IPEA/405. Such an invitation will include the identification of what the examiner considers to be the 'main invention' which will be examined if no additional fees are paid or restriction is made by the applicant." [Emphasis Supplied]

The I.S.A. did not find any lack of unity.

The standards of Markush practice and unity of invention are controlled by PCT Rule 13.2. Section 1850.III.B of the M.P.E.P. (Rev. 5) states:

B. 'Markush Practice'

"The situation involving the so-called Markush practice wherein a single claim defines alternatives (chemical or non-chemical) is also governed by PCT Rule 13.2. In this special situation, the requirement of a technical interrelationship and the same or corresponding special technical features as defined in PCT Rule 13.2, shall be considered to be met when the alternatives are of a similar nature."

"When the Markush grouping is for alternatives of chemical compounds, they shall be regarded as being of a similar nature where the following criteria are fulfilled:

(A) All alternatives have a common property or activity; and

(B)(1) A common structure is present, i.e., a significant structural element is shared by all of the alternatives; or

(B)(2) In cases where the common structure cannot be the unifying criteria, all alternative belong to a recognized class of chemical compounds in the art to which the invention pertains."

[Emphasis Supplied]

Applicants' Markush group (in Claim 1 and from the Examiner's Groups I to IV) fulfills these criteria. The Examiner has not proven factually otherwise in the record.

Section 1850. III.B also states:

"In paragraph (B)(1), above, the words 'significant structural element is shared by all of the alternatives' refer to cases where the compounds share a common chemical structure which occupies a large portion of their structures, or in case the compounds have in common only a small portion of their structures, the commonly shared structure constitutes a structurally distinctive portion in view of existing prior art, and the common structure is essential to the common property or activity. The structural element may be a single component or a combination of individual components linked together."

"In paragraph (B)(2), above, the words 'recognized class of chemical compounds' mean that there is an expectation from the knowledge in the art that members of the class will behave in the same way in the context of the claimed invention. In other words, each member could be

substituted one for the other, with the expectation that the same intended result would be achieved.”

The Office Action stated that PCT Rule 13.2 states unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The technical relationship is fulfilled by Groups I to IV. They all involve a process for the preparation of *N*-monosubstituted β -amino alcohols of formula I via direct synthesis of *N*-monosubstituted β -keto amines.

The Office Action stated that Annex B, Part 1 (b), provides that “special technical features” mean those technical features, which, as a whole, define a contribution over the prior art. The Examiner has not factually proven otherwise for Groups I to IV.

The Office Action stated that Annex B, Part 1 (e), provides combinations of different categories of claims and states:

“The method for determining unity of invention under Rule 13 shall be construed as permitting, in particular, the inclusion of any one of the following combinations of claims of different categories in the same international application:

- (i) in addition to an independent claim for a given product, an independent claims for a process specially adapted for the manufacture of the said product, and an independent claim for use of the said product, or

- (ii) in addition to an independent claim for a given process, an independent claim for an apparatus or means specially designed for carrying out the said process, or
- (iii) in addition to an independent claim for a given product, and independent claim for a process specially adapted for the manufacture of the said product, and an independent claims for an apparatus or means specially designed for carrying out the said process,..." [Emphasis Supplied]

No lack of unity is present in Groups I to IV.

The Office Action stated that this application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1. Applicants traverse this statement as being factually and legal unsupported in the record by the Examiner. The burden of proof is on the Examiner.

The Office Action stated that, due to the various classes or subclasses that variables R^1 and R^2 can fall under, e.g., R^1 can be furanyl, thienyl, naphthyl, alkyl, cycloalkyl, etc., a precise listing of inventive groups cannot be made; and that the following groups are exemplary:

Group I, Claims 1 to 8 and 21 to 25 (in part), are drawn to a process for the preparation of a compound of formula (I), wherein R^1 is C_{1-8} -alkyl and R^2 is as defined in Claim 1, classified in various subclasses of class 514.

Group II, Claims 1 to 8 and 21 to 25 (in part), are drawn to a process for the preparation of a compound of formula (I), wherein R¹ is phenyl and R² is as defined in Claim 1, classified in various subclasses of class 514.

Group III, Claims 1 to 8 and 21 to 25 (in part), are drawn to a process for the preparation of a compound of formula (I), wherein R¹ is furanyl and R² is as defined in Claim 1, classified in various subclasses of class 514.

Group IV, Claims 1 to 8 and 21 to 25 (in part), are drawn to a process for the preparation of a compound of formula (1), wherein R¹ is thienyl and R² is as defined in Claim 1, classified in various subclasses of class 514.

Group V, Claims 1 to 8 and 21 to 25, (in part), are drawn to compounds of formula (II) wherein: R¹ is furanyl, R² is as defined in Claim 9, classified in various subclasses of 548.

Group VI, Claim 9 (in part) and 11, are drawn to compounds of formula (II) wherein: R¹ is furanyl, R² is as defined in Claim 9, classified in various subclasses of class 548.

Group VII, Claims 9 (in part) and 10, are drawn to compounds of formula (II) wherein: R¹ is thienyl, R² is as defined in Claim 9, classified in various subclasses of class 548.

Group VIII, Claim 9 (in part), is drawn to compounds of formula (II) wherein: R¹ is benzo(b)thienyl, R² is as defined in Claim 9, classified in various subclasses of class 548.

Group IX, Claim 12 (in part), is drawn to compounds of formula (VIII), classified in claims 548.

Group X, Claims 13 to 20 and 26 and 30 (in part), are drawn to a process for the preparation of a compound of formula (II), wherein R¹ is C₁₋₈-alkyl and R² is as defined in Claim 1, classified in various subclasses of class 514.

Group XI, Claims 13 to 30 and 26 to 30 (in part), are drawn to a process for the preparation of a compound of formula (II), wherein R¹ is phenyl and R² is as defined in Claim 1, classified in various subclasses of class 514.

Group XII, Claims 13 to 20 and 26 to 30 (in part), are drawn to a process for the preparation of a compound of formula (II), wherein R¹ is furanyl and R² is as defined in Claim 1, classified in various subclasses of class 514.

Group XIII, Claims 13 to 20 and 26-30 (in part), are drawn to a process for the preparation of a compound of formula (II), wherein R¹ is thienyl and R² is as defined in Claim 1, classified in various subclasses of class 514.

The Office Action stated that, in accordance with 37 CFR 1.499, applicants are required, in reply to this Action, to elect a single invention to which the claims must be restricted. Applicants traverse this restriction requirement for the reasons set out in this amendment. Applicants elect with traverse the invention of Group I. Claims 1 to 8, 21 to 25, 30 and 31 are drawn to the invention of Group I.

Applicants request that the Examiner modify the restriction requirement so that Groups I to IV are combined as one group for restriction purposes. Applicants elect a group that is a combination of Groups I to IV (drawn to Claims 1 to 8, 21 to 25, 30 and 31) if the Examiner will combine them in such manner under the restriction requirement.

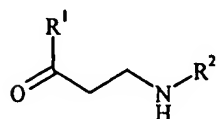
The Office Action stated: that, again, this list is not exhausted, as it would be impossible under the time constraints due to the sheer volume of subject matter

instantly claimed; that, therefore, applicants may choose to elect a single invention by identifying another specific embodiment not listed in the exemplary groups of the invention and examiner will endeavor to group the same; and that, if applicants are unable to elect a single invention, applicants may instead choose to elect a specific compound and the Examiner will attempt to group it. Applicants are fully aware of the time limitations place upon Examiners during the examination process, but note also that it is unfair to place financial burden an applicant by excessive restriction requirements.

The Office Action stated that the claims herein lack unity of invention under PCT Rule 13.1 and 13.2 since the compounds defined in the claims lack a significant structural element qualifying as the special technical feature that defines a contribution over the prior art. Applicants traverse this statement as being a mere speculative statement that has not been shown to be so by facts and technical analysis by the Examiner in the record. The burden of proof is upon the Examiner and he has not carried his burden of proof.

The Office Action stated see Wilkerson, U.S. Patent No. 4,949,183, for example. The Examiner has not factually shown in the record that Wilkerson supports the Examiner's position.

The Office Action stated that the compounds claimed contain



II

, which does not define a contribution over the prior art. -This statement has nothing to do with the situation at bar. Applicants claim a process, not compounds.

The Office Action stated that the substituents vary extensively and when taken as a whole result in vastly different compounds. The compounds used in the claimed process and produced by the claimed process do not prevent unity of invention of applicants' process claims.

The Office Action stated that, accordingly, the vastness of the claimed subject matter and the complications in understanding the claimed subject matter imposes a burden on any examination of the claimed subject matter. This does not overcome the requirement that the Examiner must show lack of unity of invention (re Groups I to IV), which he has not done in the record.

Section 1893.03(d) of the M.P.E.P. (5th Rev.) states:

"1893.03(d) Unity of Invention"

* * *

"When making a lack of unity of invention requirement, the examiner must 1) list the different groups of claims and (2) explain why each group lacks unity with each other group (i.e., why there is no single general inventive concept) specifically describing the unique special technical feature in each group."

"The principles of unity of invention are used to determine the types of claimed subject matter and the combinations of claims to different categories of invention that are permitted to be included in a single international or national stage patent application. See MPEP §1850 for a detailed discussion of Unity of Invention. The basic principle is that an application should relate to only one invention or, if there is more than one invention, that applicant would have a right

to include in a single application only those inventions which are so linked as to form a single general inventive concept.”

“A group of inventions is considered linked to form a single general inventive concept where there is a technical relationship among the inventions that involves at least one common or corresponding special technical feature. The expression special technical features is defined as meaning those technical features that define the contribution which each claimed invention, considered as a whole, makes over the prior art.”

“A process is ‘specially adapted’ for the manufacture of a product if the claimed process inherently produces the claimed product with the technical relationship being present between the claimed process and the claimed product. The expression ‘specially adapted’ does not imply that the product could not also be manufactured by a different process.” [Emphasis Supplied]

The above quotation shows that the Examiner has not established in the record any lack of unity for a group that is a combination of Groups I to IV.

Applicants retain the right to file a continuing and/or divisional application drawn to the non-elected inventions.

The several amendments to the specification find support on page 1, line 10, of the specification.

Reconsideration of the restriction requirement in view of the above is requested.

Respectfully submitted,

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<p>CERTIFICATE OF MAILING</p> <p>I hereby certify that this correspondence of is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop Patent Extension, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on <u>Feb. 12, 2007</u>.</p> <p><u>Virgil H. Marsh</u> FISHER, CHRISTEN & SABOL 1725 Street, N.W., Suite 1108 Washington, D.C. 20006</p>
